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EXAMINER	
PELLEGRINO, BRIAN E	

ART UNIT	PAPER NUMBER
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,908	KAWULA, PAUL JOHN	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-20,22-27,29 and 47-53* is/are pending in the application.

4a) Of the above claim(s) *9-20 and 24-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-8,22,23,27,29 and 47-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 10/5/09 have been fully considered but they are not persuasive. Applicant argues that Santini does not have an attachment region disposed within the stent surface. However, the Examiner respectfully disagrees because clearly as seen in Fig. 9A of Santini it shows the stent has an inner surface defining the attachment region in which a ceramic component is disposed within the lumen of the stent. In addition Santini discloses the ceramic component drug reservoir can be within the stent as stated in col. 14 and thus is within the stent surface. It is also noted that it can be said that the "region" also comprises an indentation or aperture as clearly seen in the figure and stated by Santini on the figure. It is also noted that the claim (27) states the ceramic component is on the attachment region as recited in part c) of the claim. Thus, Santini can be said to disclose an attachment region within the stent surface. Second Applicant argues that different thickness can not equate to porosity. The Examiner respectfully disagrees and refers Applicant to Ragheb (6299604) which states that there is a correlation between porosity and thickness, see col. 19, lines 34,35. Thus, Applicant's assessment that there is no correlation is incorrect and Santini can be said to have a more porous ceramic and a less porous ceramic.

Applicant also argues the interpretation of "ceramic component" and the arrangement of Santini's ceramic "components" are not the same as Applicant. The Examiner respectfully disagrees because the claim recites the ceramic **component** has "a first porous ceramic or glass side and a second less porous ceramic or glass side". First the Examiner notes that the term

"component" is a broad word with no special definition or structure implied in any sense. In the context of the claim, it is just a form of matter that is made of ceramic. Second the claim only requires two different porosity ceramics to be part of the "component" with no specific arrangement since the claim does not specifically set forth how these "porous ceramics" are arranged with respect to one another. Therefore the arrangement of the porous ceramics of Santini's device as interpreted by the Examiner is within the scope of the claim as presented.

Applicant's arguments with respect to claim 6 have been considered and addressed above but also are moot in view of the new ground(s) of rejection.

Claim Objections

Claim 22 is objected to because of the following informalities: the "surface of the …" is not defined. It is interpreted as the stent body. Appropriate correction is required.

Claim 49 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 49 recites the "attachment region being defined by some removed material from the stent body" of which depends from claim 6. Claim 6 can be said to define the "attachment region" by a "*cavity* in the stent surface" and thus has some material removed since it has a base surface of the cavity.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the new limitation in claim 53, that "the first porous ceramic region of the ceramic component is in intimate contact with and extending from the second porous ceramic region of the ceramic component" was not found in the written disclosure.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 27,29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santini et al. (6656162) in view of Brandau et al. (6709379). Santini et al. show (Figs. 9A-9C) the medical device is a stent. Fig. 2A illustrates a substrate **210** made of metal (col. 4, lines 4,8) that has within its surface a cavity and attachment region **220**. Figs. 6A,6B illustrate that within the surface is a ceramic component, col. 12, line 14. It can also be seen there is a second ceramic component (col. 8, lines 49,50,53,55) in the form of a cap to be on the opposite side of the first ceramic component and the attachment region on the opposing side of the first ceramic component. It can be interpreted that the second ceramic component or cap is more porous than the first ceramic component (piezoelectric element) since it is thinner, col. 8, lines 56-58). Ceramics are known to be porous. It can also be seen (Figs. 6A,6B) the ceramic *regions* or sides collaboratively contain a drug, col. 9, lines 58-67. It is noted that Santini discloses layered ceramics can be used, col. 4, lines 7,8. However, Santini does not explicitly disclose the ceramics

including an oxide layer between the ceramic component and the substrate. Brandau et al. teach that an oxide layer is formed for depositing layers on a substrate, col. 8, lines 2,3,15-20. It would have been obvious to one of ordinary skill in the art to utilize an oxide layer as taught by Brandau et al. with the stent of Santini et al. such that it secures the ceramic component to the substrate.

Claims 6-8,22,49,53 are under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Santini et al. '162 in view of Gustavson (5108432). Santini et al. is explained above. Santini et al. does disclose the ceramic drug delivery component can be incorporated into the stent body, col. 14, lines 63-65. However, alternatively Santini et al. does not explicitly show the embodiment of the ceramic component attached within the surface cavity of a stent body. Gustavson teaches (Fig. 5) a cavity **16** in the body of an implant **10** with a base surface **25** for attachment to a porous component **24**. Gustavson further teaches (Fig. 6) the cavity allows for cells to interact at the same surface level by placing the porous component in the cavity, col. 1, line 68, col. 2, lines 1,2,65-68. It would have been obvious to one of ordinary skill to place the ceramic component of Santini et al. within the stent surface per the teaching of Gustavson such that it provides the optimal condition for the tissue cell interface so the proper stabilization can occur and cell exposure to the drugs. Regarding claim 8, Santini discloses numerous drugs as recited in the claim, see col. 9, lines 36-65. With respect to claim 53, since each drug reservoir includes different ceramic porous component portions forming the delivery system it can be said that therefore the first and second ceramic porous regions are in intimate "contact" or communication with one another.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santini et al. '162 in view of Gustavson '432 as applied to claim 22 above, and further in view of Alt (6099561). Santini fails to disclose the specific metal material being steel or nitinol. Alt teaches the surface of the stent is metal, col. 6, lines 50-55 and the stent metal can be steel or nitinol, col. 7, lines 44-49. It would have been obvious to one of ordinary skill in the art to use a known metal as steel or nitinol as taught by Alt with the stent of Santini et al. as modified with Gustavson such that it provides the necessary properties desired. Selecting known materials for stents only involves routine skill in the art.

Claims 47,48,50,52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santini et al. '162 in view of Gustavson '432 as applied to claim 6 above, and further in view of Brandau et al. '379. Santini et al. as modified with Gustavson is explained above. However, Santini in view of Gustavson does not explicitly disclose the ceramics including an oxide layer between the ceramic component and the substrate. Brandau et al. is also explained supra. Thus, it would have been obvious to one of ordinary skill in the art to place an oxide layer as taught by Brandau et al. for fusing or attaching the ceramic component to the substrate surface in the stent surface of Santini et al. as modified with Gustavson such that it can be properly secured without risk of detachment. Regarding claim 50, Santini fails to disclose the specific ceramic materials. Brandau et al. teach a ceramic cover layer being a ceramic oxide, col. 8, lines 21-24. It would have been obvious to one of ordinary skill in the art to select a known oxide as taught by Brandau et al. to use as the ceramic region on the Santini et al. stent since such a modification only involves routine skill in the art. With respect to claim 52, the incorporation of an oxide

layer would result in a layer with the same thermal characteristics as the ceramic component by forming the oxide from the same material.

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santini et al. '162 in view of Gustavson '432 as applied to claim 6 above, and further in view of Pope et al. (6290726). Santini as modified with Gustavson fail to disclose the specific ceramic material being quartz. Pope et al. teach a quartz ceramic can be used in the body for prostheses for low friction and long life, col. 11, lines 10-12, 35,36. It would have been obvious to one of ordinary skill in the art to select a known material, such as quartz as taught by Pope et al. to use as the ceramic region on the Santini et al. in view of Gustavson stent since such a modification only involves routine skill in the art. Such a modification provides a smooth surface for blood flow and is corrosion resistant.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738